

## **Aventis Pharmaceuticals**

March 6, 2002



Via fax and UPS

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. 01D-0435**

Draft Guidance on Electronic Common Technical Document Specification [66FR 59431, November 28, 2001]

Dear Sir/Madam:

Aventis Pharmaceuticals Inc. would like to thank you for the opportunity to comment on the above-referenced draft guidance entitled "Electronic Common Technical Document Specification". The document defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. We offer the following comments/clarification for your consideration.

**Folder structure and indexing**

With regard to folder structure and naming conventions detailed for each module, we suggest that all folders and subsequent folders be numbered with the corresponding CTD numbering section. This would enhance clarity and quality control, and be consistency with XML indexation scheme.

01D-0435

C 4

Some screenshots are provided below for illustration.

Figure 5-1 – Proposal for the folder structure of Module 2 (Appendix 5 Page 5-1)

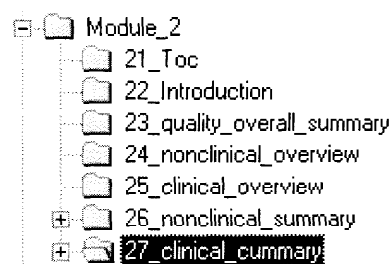
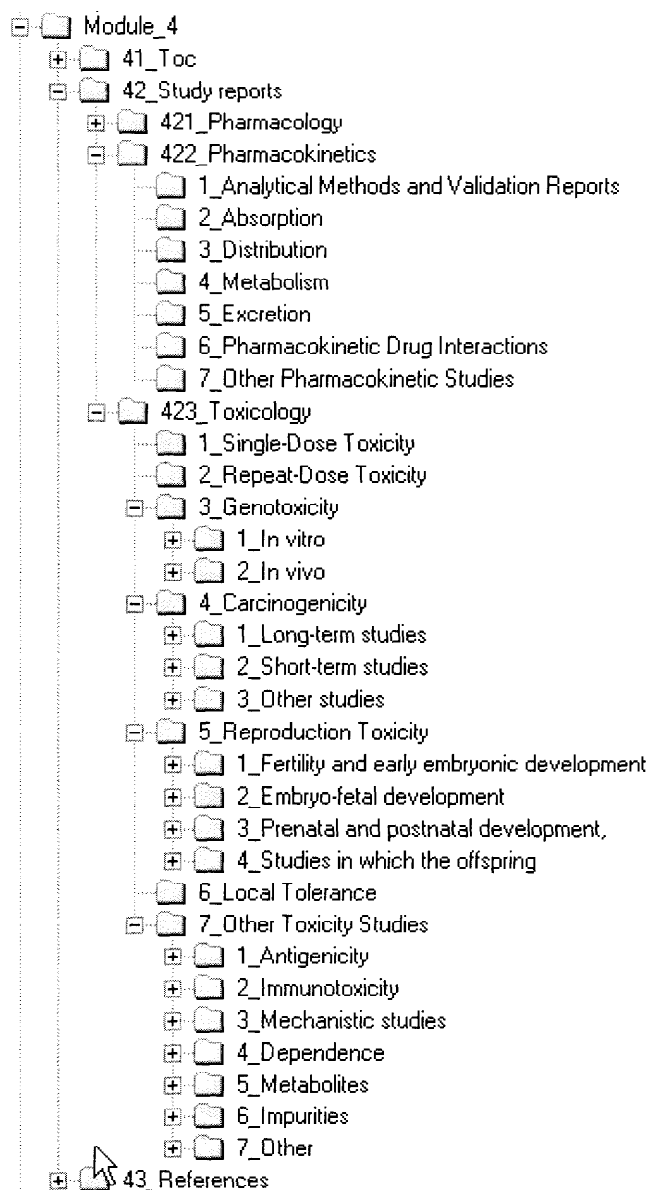


Figure 7-1 – Proposal for the folder structure of Module 4 (Appendix 7 Page 7-3)



Note 1: A folder has been systematically created for consistency in the structure presentation whether or not it contains only one file.







Note 2: Screenshots do not represent eCTD specification and conventions necessarily. They are provided only as a means to illustrate the use of folder numeric indexation.

### **File naming conventions and indexing**

We would like to have a similar level of flexibility to index files included in a folder. Indexing would allow sorting, and therefore facilitate quality control. It would also standardize file names independently of the granularity adopted by the company.

A screenshot of the Clinical summary section is provided below for illustration.

*Proposal for file naming conventions (including prefix number)*

 271\_Clinical\_WS-Biopharmaceutics.pdf  
 272\_Clinical\_WS-Pharmacology.pdf  
 273\_Clinical\_WS-Efficacy.pdf  
 274\_Clinical\_WS-Safety.pdf  
 275\_Clinical\_WS-Listing.pdf  
 276\_Clinical\_TS.pdf

### **Cross-references**

The issue concerning cross-reference between documents is not addressed in the draft guidance.

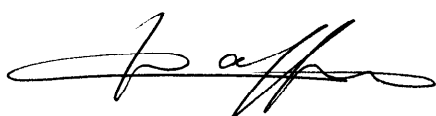
Since we are moving from a volume to a document approach according to Appendix 12, page 12-4, and considering XML conventions for cross-referencing documents (Xpath and Xlink), we strongly recommend basic recommendations to be included in the guidance.

In addition, the draft Guidance for Industry “Submitting Marketing Applications according to the ICH-CTD format – General Considerations” August 2001 recommends that the page numbering should be at the document level and not at the volume or module level. Use of tab identifiers is required to demarcate each document, attached as an appendix within a document, and therefore eliminate the volume approach (page 12, K. Pagination).

For cross-referencing between documents, will there be different requirements according to regional specification? Will there be different requirements for eCTD *versus* paper CTD?

On behalf of Aventis Pharmaceuticals Inc. we appreciate the opportunity to comment on the draft guidance for industry on Electronic Common Technical Document Specification, and thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Caffé', with a stylized, flowing script.

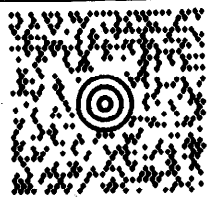
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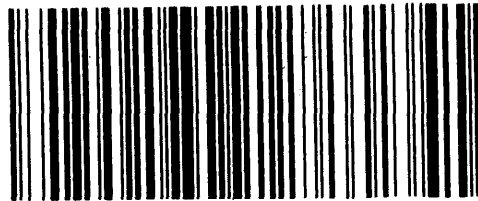
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